



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : <b>A61F 5/08, A61M 15/00, 16/00, A62B 7/00</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 98/32403</b></p> <p>(43) International Publication Date: 30 July 1998 (30.07.98)</p>
<p>(21) International Application Number: PCT/US98/01513</p> <p>(22) International Filing Date: 28 January 1998 (28.01.98)</p> <p>(30) Priority Data: 08/791,760 29 January 1997 (29.01.97) US</p> <p>(71)(72) Applicants and Inventors: CRONK, Peter, J. [US/US]; 919 McElwee Road, Moorestown, NJ 08057 (US). CRONK, Kristen [US/US]; 919 McElwee Road, Moorestown, NJ 08057 (US).</p> <p>(74) Agent: CRONK, Peter, J.; Duane, Morris &amp; Heckscher LLP, One Liberty Place, Philadelphia, PA 19103 (US).</p>		<p>(81) Designated States: AU, BR, CA, CN, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>With international search report.</i> <i>With amended claims.</i></p>
<p>(54) Title: EXTERNALLY MOUNTED MEDICATED NASAL DILATOR</p> <p>(57) Abstract</p> <p>A nasal dilator (100) comprising an elongated substrate (30), a pressure sensitive adhesive layer (32) disposed on the bottom surface of the substrate, a resilient member (60) bonded to the substrate, and a medication (50), aromatic or transdermal, disposed on a portion of the dilator.</p> <div data-bbox="808 1150 1385 1816" data-label="Image"> </div>		

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## EXTERNALLY MOUNTED MEDICATED NASAL DILATOR

**Field of the Invention**

5 This invention relates to dilators for easing the breathing of patients, and more particularly to medicated nasal dilators for preventing outer wall tissue of nasal passages from drawing in during breathing while providing medication to the patient.

**Background of the Invention**

10 Nasal dilators have been suggested for aiding breathing through the nose. There have been traditionally two types of dilators which have been effective in humans. One type uses small rings or cages connected to a resilient structure. The rings are inserted into each nasal passage while the resilient structure spreads to provide unobstructed breathing. These dilators have been criticized because they are often uncomfortable to wear. Since the cages or rings are inserted into contact with sensitive nasal tissue, they have been known to cause irritation and itching. Such devices are disclosed in U.S. Patent Number 3,710,799 to Caballero and the NOZOVENT dilator disclosed in Petruson  
15 D310,565.

20 More recently, advancements have been made in nasal dilators which attach to the outer wall tissue of the nose and aide in preventing the inner nasal tissue from drawing in during breathing. Such dilators include a flexible strip of material adhesively attached to a substrate. The dilator is fastened to the nose and the resilient material acts to keep the left and right nasal passages from drawing in or collapsing during inhalation. This usually occurs due to a malformation, such as a deviated septum or due to swelling during allergic reactions and the like. Examples of nasal dilators which are adhesively attached to the outer skin of a human nose are disclosed in Doubek et al., U.S. 5,533,503 and Muchin, U.S. 5,546,929.

25 While conventional nasal dilators are being used by a greater number of people, there is still a need to further improve the breathing of those individuals to a greater degree than can be established by mere mechanical manipulation of their nasal tissue.

### Summary of the Invention

Nasal dilators and methods of easing breathing are provided by this invention. The first group of preferred dilators include an elongated substrate having a pair longitudinal sides, a pair of transverse ends and top and bottom surfaces. Disposed on the bottom surface of the substrate is a pressure sensitive adhesive. The substrate also includes a resilient member bonded to its surface to provide a gentle expanding force to a nasal wall tissue when the dilator is adhesively attached to a nose. In an important improvement over the prior art, an aromatic medication is disposed on a portion of the dilator so that it can be inhaled through the nose of the wearer during breathing.

This invention combines the spring action of adhesively applied nasal dilators with inhaleable aromatics. Such an accommodation has the potential to produce synergistic benefits for patients who have not been entirely satisfied by either non-medicated dilators, or over-the-counter decongestant medication, some of which can cause drowsiness.

In another embodiment of this invention, a method of substantially preventing the wall tissue of a nose from drawing in during breathing is provided. The method includes providing a nasal dilator including a substrate having disposed thereon a pressure sensitive adhesive layer on a first surface and a resilient member bonded to a second surface. Impregnated into the substrate is an aromatic medication for helping the patient breathe easier. The method further includes applying the pressure sensitive adhesive layer across a nose whereby the resilient member provides a gentle expanding force to the nasal wall tissue while the aromatic medication is being inhaled.

Further embodiments of this invention include transdermal medications and resilient scrims or sheet layers bonded to the substrate for minimizing the expense of continuous processing of the dilators of this invention.

### **Brief Description of the Drawings**

The accompanying drawings illustrate preferred embodiments of the invention as well as other information pertinent to the disclosure, in which:

5       FIG. 1: is a partial front perspective view of a man wearing the preferred nasal dilator of this invention;

      FIG. 2: is a top planar view the nasal dilator of this invention with a partial peel back view of the adhesive layer;

      FIG. 3: is a side elevation, cross-sectional, exploded view of the nasal dilator of FIG. 2;

10       FIG. 4: is a top planar view of a preferred resilient member, including the periphery of the substrate of the nasal dilator in phantom; and

      FIG. 5: is a top planar view of an alternative resilient member consisting of a reinforcing scrim also depicting the periphery of the substrate in phantom.

### **Detailed Description of the Invention**

15       This invention provides nasal dilators and methods for substantially preventing a nasal wall tissue of a nose from drawing in during breathing. As used herein, the term "aromatic" medication refers to substances and compounds which can be consumed by inhaling through the nose, such as a medicated vapor or gas. Such substances should have some efficacy in helping patients breathe easier or better.

20       With reference to the figures and in particular, FIGS. 1-3 thereof, there shown a preferred nasal dilator 100 sized to fit across the nose of the wearer so as to engage the outer wall tissue of the left and right nasal passages of the wearer. As shown in FIGS. 2-3 the nasal dilator 100 includes an elongated substrate 30 having a pair of longitudinal sides, a pair of transverse ends and top and bottom surfaces thereon. Disposed on a  
25       bottom surface of the substrate 30 is an adhesive layer 32 for permitting easy attachment to the wearer's skin. Also attached to the substrate is a resilient member 60 which provides a gentle expanding force to the nasal wall tissue when the dilator is adhesively attached to the nose. Finally, an aromatic medication 50 is disposed on a portion of the dilator so as to be inhaled through the nose of the wearer during breathing.

In further embodiments of this invention, the dilator 100 can include a backing layer 40. The backing layer 40 and resilient member 60 are desirably bonded to the substrate 30 using pressure sensitive adhesive layers 42 and 62. As shown in FIG. 3 the aromatic medication can be disposed on any surface of the dilator 100. Preferably the aromatic medication 50 is disposed on an absorbent layer portion of the dilator 100. The absorbent layer portion can be a separate absorbent layer or a portion of the elongated substrate 30 or backing layer 40. Alternatively, the aromatic medication can be disposed in one of the adhesive layers in an admixture or segregated form. Finally, a release paper strip 10 can be added over the pressure sensitive adhesive layer 32 prior to packaging the strip for sale.

The elongated substrate 30 of this invention may include any thin, flexible, breathable material for maximizing comfort. Preferably this material permits the passage of air and moisture vapor, such as perspiration. The elongated substrate can include, for example, a woven or non-woven fabric material, such as non-woven, polyester fabric. One good example is a fabric produced by DuPont E. I. de Nemours & Co., Inc. under the trademark Sontara®. Alternatively, the elongated substrate 30 can include a thermoplastic woven or non-woven fabric, such as spun-bonded polyethylene or polypropylene. The substrate 30 can also be treated with the aromatic medication 50 of this invention, along with a hydrophilic or hydrophobic additive for absorbing or repelling sweat or moisture on a selective basis.

Attached to the substrate 30 on the nose skin-facing side or bottom surface of the substrate 30 is an adhesive layer 32. This adhesive layer, along with optional adhesive layers 62 and 42 can be made of a pressure sensitive biocompatible adhesive material. As used herein, "pressure-sensitive" refers to any releasable adhesive or releasable tenacious means. Adhesive compositions suitable for nasal dilators include water-based pressure-sensitive adhesives, such as acrylate adhesives, thermoplastics "hot melt" adhesives, two-sided adhesive tape, elastomer-based adhesives, and acrylic adhesives. Good examples include 3M1509 double-sided medical tape provided by 3M Inc., St. Paul, Minnesota. This product is a double-sided transparent polyethylene film, coated on both sides with a hypoallergenic, pressure-sensitive acrylate adhesive, supplied on a paper liner. Of

course, adhesive layers 62 and 42 need not be a pressure-sensitive type at all, since once the resilient member 60 and backing layer 40 are adhered to the substrate 30, it is undesirable for these layers to separate during application or removal of the dilator from the nose.

5           The resilient member 60 of this invention preferably includes one or more spring strips 60a which can be die-cut from spring ribbon material. Good examples of spring ribbon material include biaxially oriented polyester that is approximately 0.01 inches thick, but polyethylene or polypropylene strips of like thickness would also provide expanding force to the dilator 100. Fiber additions to the resin of the spring strips 60a,  
10           such as, glass, graphite, carbon or boron will also improve resiliency.

          Alternatively, as shown in FIG. 5, a resilient layer, such as scrim 60b can be disposed within, or substantially along the perimeter 11 of the substrate 30 or outer peripheral region of the dilator 100. The resilient layer can be a woven oriented mat, fabric or material, or a non-woven mat material of fibers which are either adhesively or  
15           melt bonded together. Such fibers can include thermoplastic or thermosetting polymers. Examples include thermoplastic fibers, such as nylon, polyethylene, and polyester fibers, for example SPECTRA or COMPET fibers sold by Allied Signal Corp., Kevlar® 29, 49 or 149 aramid fibers sold by DuPont, glass, such as E-glass and S-Glass fibers, graphite fibers, carbon fibers, boron fibers, or combinations of these fibers. The resilient member,  
20           whether including spring strips 60a or a resilient scrim 60b or sheet layer (not shown) is preferably joined together in a webbing operation either by melt bonding, adhesive bonding or ultrasonic bonding. In conventional operations, a ribbon of resilient material and substrate material are adhesively joined together as they are fed into an overlapping position in a die or roller. Adhesive layers 42 and 62 are used to join the backing layer,  
25           resilient member 60 and elongated substrate 30 together prior to die-cutting to form the final periphery 11 of the dilator 100. The adhesive layers 42, 62 and 32 can be applied by spray, roll or knife, as is customary in the web-processing industry.

          An important advantage of the resilient layer, such as scrim 60b or a sheet layer, as opposed to a pair of discrete spring strips 60a of this invention, is the elimination of a  
30           careful placement operation prior to die-cutting. Such an expensive step becomes

unnecessary, since the resilient layer preferably conforms generally to the perimeter 11 of the final die-cut dilator. This can eliminate waste and minimize much of the expense of the webbing operation. It also provides for a more uniform spring action along most or all of the surface area of the dilator 100.

5           Additionally, this invention contemplates employing thermoplastic materials in the backing layer 40 and substrate 30, and alternatively, with respect to the resilient member 60 or layer. When thermoplastic materials are used, this invention enables inexpensive melt-bonding of the layers of material, with heat and pressure, to provide a composite nasal dilator structure. Melt-bonding could eliminate the need of additional  
10           adhesive layers 42 and 62 and provide a greater structural integrity to the dilator no matter what form of resilient member is employed. However, resilient scrim 60b is ideally suited for thermoplastic bonding of layers since it has pores for permitting softened thermoplastic material to bond between the fibers or filaments, further increasing the strength of the dilator 100, without requiring a lot of material.

15           In a further important aspect of this invention, the dilator can include an aromatic medication 50, transdermal medication, or both. Good examples of aromatic medications include camphor, eucalyptus oil, peppermint oil, menthol, methy salicylate, bornyl acetate, lavender oil, or a combination of these. Transdermal decongestants and antihistamines are also available, such as diphenhydramine and triprolidine transdermal  
20           antihistamine, available from Proctor and Gamble Co., Inc., Cincinnati, Ohio; others include ephedrine, dimethindene, epinastine, emedastine, and clonidine. These aromatic and transdermal medications can be mixed within adhesive layer 32, as in, for example, a dispersion-type transdermal patch formulation from acrylate copolymer adhesive or a lecithin gel based matrix. Alternatively, a rate controlling membrane could be used, such  
25           as Eudragit RL-100.

          From the foregoing, it can be realized that this invention provides improved nasal dilators which include possibly synergistic combinations of mechanical and medicated aromatic or transdermal compositions. Also included are material processing improvements which add improved functionality and reduce the overall cost of the  
30           product. The dilators and methods of this invention are useful for helping individuals



with deviated septums and athletes who desire more oxygen during a performance. Although various embodiments have been illustrated, this is for the purpose of describing, but not limiting the invention. Various modifications which will become apparent to one skilled in the art, are within the scope of this invention described in the attached claims.

We Claim:

1. A nasal dilator 100 for substantially preventing a nasal wall tissue of a nose from drawing in during breathing, characterized by:

an elongated substrate 30 having a pair of longitudinal sides, a pair of transverse ends, and top and bottom surfaces thereon;

a pressure sensitive adhesive layer 32 disposed on said bottom surface of said substrate;

a resilient member 60 bonded to said substrate to provide a gentle expanding force to said nasal wall tissue when said dilator 100 is adhesively attached to said nose; and

an aromatic medication 50 disposed on a portion of said dilator 100, said aromatic medication 50 being inhaled through said nose during breathing.

2. A nasal dilator of Claim 1 wherein said resilient member includes a resilient band, resilient fibers or a resilient layer.

3. The nasal dilator of Claim 1 wherein said aromatic medication includes one or more of: camphor, eucalyptus oil, peppermint oil, menthol, methyl salicylate, bornyl acetate, lavender oil, or a combination thereof.

4. The nasal dilator of Claim 1 further including an aromatic antihistamine or decongestant.

5. The nasal dilator of Claim 1 further including a fibrous absorbent layer bonded to said substrate.

6. The nasal dilator of Claim 5 further including a transdermal antihistamine or decongestant.

7. The nasal dilator of any one of claims 1-6 wherein said aromatic medication is mixed within said adhesive layer.

8. The method of Claim 1 wherein said aromatic medication is substantially activated upon being warmed by body heat.

5 9. A nasal dilator 100 for substantially preventing a nasal wall tissue of a nose from drawing in during breathing, characterized by:

an elongated substrate 30 having a pair of longitudinal sides, a pair of transverse ends, and a top and bottom surface thereon;

10 a pressure sensitive adhesive layer 32 disposed on said bottom surface of said substrate;

a resilient member 60 bonded to said substrate to provide a gentle expanding force to said nasal wall tissue when said dilator is adhesively attached to said nose; and

15 a transdermal medication 50 disposed on said bottom surface for providing breathing relief to said patient.

10. The nasal dilator of Claim 9 wherein said transdermal medication includes an antihistamine or decongestant.

## AMENDED CLAIMS

[received by the International Bureau on 27 May 1998 (27.05.98);  
original claims 1-10 replaced by amended claims 1-10 (2 pages)]

1. An externally mounted nasal dilator 100 for substantially preventing a nasal wall tissue of a nose from drawing in during breathing, characterized by:  
an elongated flexible, resilient member having a top and a bottom surface thereon;  
a pressure sensitive adhesive layer 32 disposed on said bottom surface of said resilient member;  
said resilient member providing a gentle expanding force to said nasal wall tissue when said dilator 100 is adhesively attached to said nose by said pressure sensitive adhesive layer 32; and  
an aromatic or transdermal substance 50, or both, disposed on said dilator.
2. A nasal dilator of Claim 1 wherein said resilient member includes a ribbon, fibers, a woven layer, a non-woven layer, a scrim, a composite, a sheet layer, or a combination thereof.
3. The nasal dilator of Claim 1 wherein said aromatic substance includes one or more of: camphor, eucalyptus oil, peppermint oil, menthol, methyl salicylate, bornyl acetate, lavender oil, or a combination thereof.
4. The nasal dilator of Claim 1 wherein said aromatic or transdermal substance comprises an antihistamine or decongestant.
5. The nasal dilator of Claim 1 wherein said resilient member includes a fibrous absorbent layer portion.
6. The nasal dilator of any one of claims 1-5 wherein said aromatic or transdermal substance is mixed within said adhesive layer.

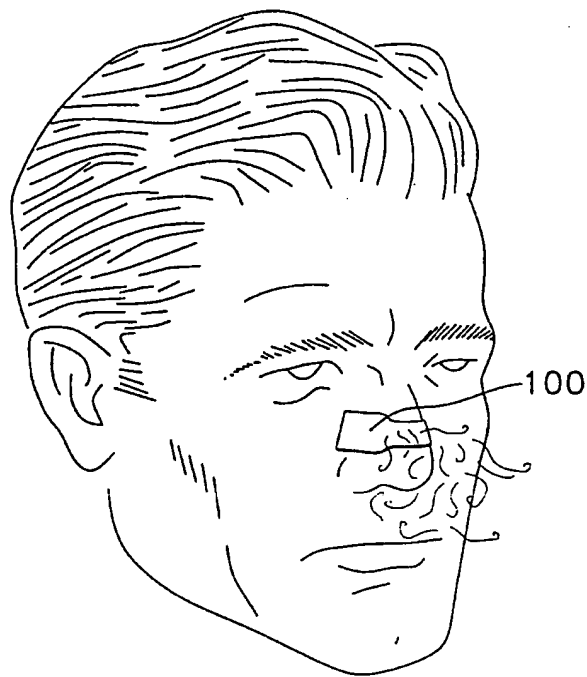
7. The method of Claim 1 wherein said aromatic or transdermal substance is substantially activated upon being warmed by body heat.

8. A method of easing a patient's breathing by adhesively applying an elongated flexible substrate 30 to an external nasal wall tissue of the patient, said substrate 30 having a pair of longitudinal sides, a pair of transverse ends, and top and bottom surfaces thereon, said substrate 30 including a pressure sensitive adhesive layer 32 disposed on said bottom surface; said method characterized by: providing an aromatic or transdermal substance 50 on said substrate 30 for easing said patient's breathing.

9. The method of Claim 8, wherein said medication is disposed within an absorbent portion of said substrate, a dispersion-type transdermal patch formulation, a gel based matrix or a rate-controlling membrane.

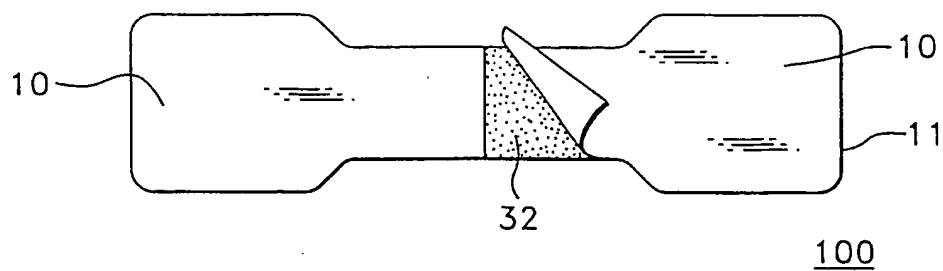
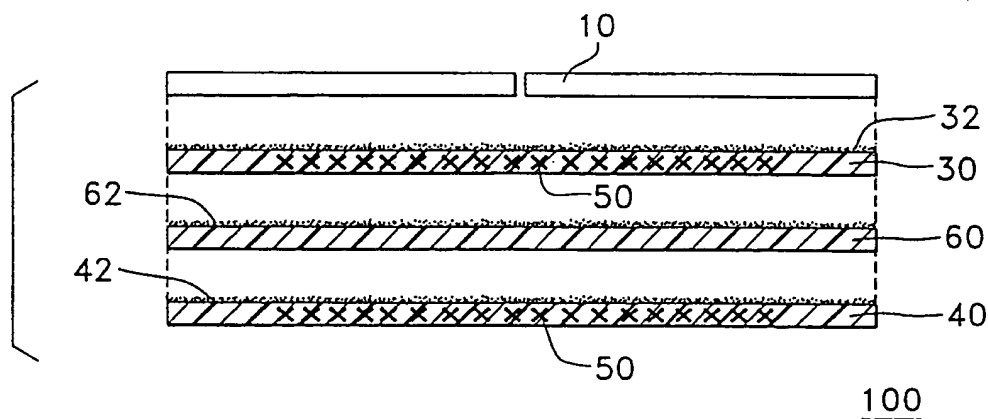
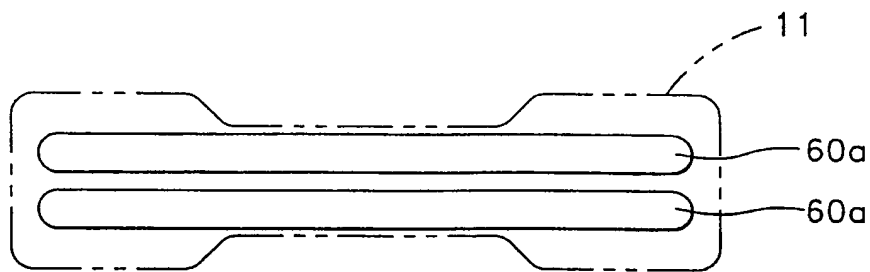
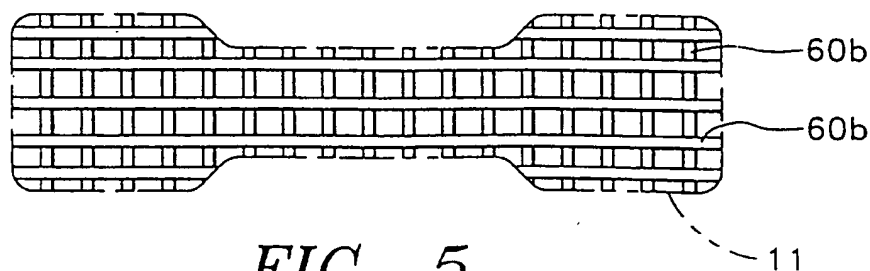
10. The method of Claim 8, wherein said medication includes an antihistamine, decongestant, or aromatic medication.

1 / 2



*FIG. 1*

2 / 2

*FIG. 2**FIG. 3**FIG. 4**FIG. 5*

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/01513

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 5/08; A61M 15/00, 16/00; A62B 7/00

US CL : 128/200.24, 207.14, 204.13; 606/199, 204.45

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## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/200.24, 207.14, 204.13, 207.18, 912, 848, DIG. 26; 606/199, 204.45; 602/41, 47, 54-59, 74, 902

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
none

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5553605 A (MUCHIN) 10 September 1996. See entire document.	1-10
A	US 5476091 A (JOHNSON) 19 December 1995. See entire document.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search

24 MARCH 1998

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28 APR 1998

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